

is selected from the group consisting of total Hb, oxy-Hb, and "total Hb minus met-Hb."

REMARKS

Claims 1-83 and 96-97 are pending in this application.

Claims 63 and 73 have been amended to correct minor informalities. Claims 1, 9, 10, 18-20, 45, 67, 77, 73, and 80 have been amended.

Applicant submits that the present application is in condition for allowance, and respectfully requests issuance of a Notice of Allowance.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

Respectfully submitted,



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MARKED-UP VERSION OF THE CLAIMS:

1. (Amended) A method of monitoring calibration of a spectrophotometric apparatus comprising one or more calibration algorithms for one or more analytes comprising:
 - i) measuring absorbance of a quality control material with said apparatus to obtain a measurement, said quality control material exhibiting an absorbance spectra characterized as having a negative slope for a continuous spectral segment from about 5 nm to about 200 nm in length said spectral segment including a principal calibration wavelength for said one or more analytes;
 - ii) calculating one or more [concentrations] values from said measurement using said one or more calibration algorithms; and
 - iii) comparing said one or more [concentrations] values with an assigned value given to said quality control material for each of said one or more analytes [; and iv) determining if there is a violation of a pre-established quality control rule], thereby monitoring said one or more calibration algorithms of said apparatus.

9. (Amended) A method of monitoring calibration of a spectrophotometric apparatus comprising one or more calibration algorithms for a perflurocarbon-like blood substitute,

turbidity, or a combination thereof, wherein said turbidity is measured in concentration units of a lipid emulsion, comprising:

i) measuring absorbance of a quality control material with said apparatus to obtain a measurement, said quality control material exhibiting an absorbance spectra within the range from about 700 nm to about 1100 nm;

ii) calculating one or more [concentration] values from said measurement using said one or more calibration algorithms; and

iii) comparing said one or more [concentration] values with an assigned value given to said quality control material for each of said perflurocarbon-like blood substitute, said turbidity, or a combination thereof [; and iv) determining if there is a violation of a pre-established quality control rule], thereby monitoring said one or more calibration algorithms of said apparatus.

10. (Amended) A method of monitoring calibration of a spectrophotometric apparatus comprising one or more calibration algorithms for a perflurocarbon-like blood substitute, turbidity, or a combination thereof wherein said turbidity is measured in concentration units of a lipid emulsion, comprising:

i) measuring absorbance of a quality control material with said apparatus to obtain a measurement, said quality

control material exhibiting an absorbance spectra characterized as having a negative slope for a continuous spectral segment from about 5nm to about 400nm within the range of the absorbance spectra from about 700 nm to about 1100 nm;

ii) calculating one or more [concentration] values from said measurement using said one or more calibration algorithms; and

iii) comparing said one or more [concentration] values with an assigned value given to said quality control material for [of] said one or more of a perflurocarbon-like blood substitute, turbidity, or a combination thereof, wherein said turbidity is measured in [concentration] units of a lipid emulsion [; and iv) determining if there is a violation of a pre-established quality control rule], thereby monitoring said one or more calibration algorithms of said apparatus.

18. (Amended) A reagentless method for determining the concentration of one or more analytes in a sample in a spectrophotometric apparatus comprising at least one primary calibration algorithm comprising:

i) monitoring calibration of said apparatus as defined in claim 1;

[ii) establishing that there is no violation of a pre-established quality control rule:]

[iii)] ii) measuring absorbance values of said sample;
[iv)] iii) calculating an order derivative of absorbance of said sample; and
[v)] iv) calculating a concentration of said one or more analytes in said sample, by applying said at least one primary calibration algorithm to said order derivative of absorbance value.

19. (Amended) A reagentless method for determining the concentration of one or more analytes in a sample in a spectrophotometric apparatus comprising at least one primary calibration algorithm comprising:

i) monitoring calibration of said apparatus as defined in claim 9;
[ii) establishing that there is no violation of a pre-established quality control rule:]

[iii)] ii) measuring absorbance values of said sample;
[iv)] iii) calculating an order derivative of absorbance of said sample; and
[v)] iv) calculating a concentration of one or more of said perfluorocarbon-like blood substitute, said turbidity, or a combination thereof, in terms of concentration of a lipid emulsion in said sample, by applying said primary calibration algorithm to said order derivative of absorbance value.

20. (Amended) A reagentless method for determining the concentration of one or more analytes in a sample in a spectrophotometric apparatus comprising at least one primary calibration algorithm comprising:

i) monitoring calibration of said apparatus as defined in claim 10;

[ii) establishing that there is no violation of a pre-established quality control rule:]

[iii)] ii) measuring absorbance values of said sample;

[iv)] iii) calculating an order derivative of absorbance of said sample; and

[v)] iv) calculating a concentration of one or more of said perflurocarbon-like blood substitute, said turbidity, or a combination thereof, in terms of concentration of a lipid emulsion in said sample, by applying said primary calibration algorithm to said order derivative of absorbance value.

45. (Amended) A method of monitoring the calibration of a reagentless spectrophotometric apparatus comprising one or more calibration algorithms for one or more analytes in a sample, said method comprising:

i) measuring absorbance of a quality control material with said reagentless spectrophotometric apparatus to obtain one

or more measurements, said quality control material comprising one or more substances that absorb electromagnetic radiation, whereby predicted values for said one or more analytes can be obtained ;

ii) calculating one or more of said predicted values from said one or more measurements; and

iii) comparing said one or more of said predicted values with one or more assigned values given to said quality control material for said one or more analytes [; and

iv) determining if there is a violation of a pre-established quality control rule], thereby monitoring said calibration algorithms of said reagentless spectrophotometric apparatus.

67. (Amended) A quality control material for use in a reagentless spectrophotometric apparatus, comprising, one or more substances that mimic one or more analytes in whole blood, serum, plasma, urine, synovial fluid or cerebrospinal fluid.

73. (Twice Amended) A quality control material for use in a reagentless spectrophotometric apparatus, comprising, one or more substances that mimics an indicator of hemolysis, wherein said one or more substances are selected from the group consisting of total Hb, oxy-Hb, "total Hb minus met-Hb,"

cyanmet-Hb, amaranth, acid fuchsin, basic fuchsin,ponceau S, chromotrope 2R, phenol red, crystal ponceau, methyl orange, a Hb-based blood substitute, [oxy-Hb,] carboxy-Hb, [cyanmet-Hb,] a polymer, and a protein, and wherein said quality control material is exposed to atmospheric conditions.

77. (Amended) A quality control material for use in a reagentless spectrophotometric apparatus, comprising, one or more substances that mimic an indicator of hemolysis, wherein said indicator of hemolysis is selected from the group consisting of total Hb, oxy-Hb and "total Hb minus met-Hb."

80. (Amended) A quality control material for use in a reagentless spectrophotometric apparatus, comprising, one or more substances that mimics one or more of, an indicator of hemolysis, biliverdin, bilirubin, methelene blue, met-Hb, a simulator of turbidity, a perflurocarbon-like blood substitute, a Hb-based blood substitute wherein said indicator of hemolysis is selected from the group consisting of total Hb, oxy-Hb and "total Hb minus met-Hb."